FDA Advisory Committee Recommends the Approval of Baricitinib 2mg, but not 4mg, for the Treatment of Moderately-to-Severely Active Rheumatoid Arthritis

April 23, 2018

INDIANAPOLIS, April 23, 2018 /PRNewswire/ -- Eli Lilly and Company (LLY) and Incyte Corporation (INCY) announced today that the U.S. Food and Drug Administration's (FDA) Arthritis Advisory Committee recommended approval of the 2-mg dose of baricitinib, a once-daily oral medication for the treatment of moderately-to-severely active rheumatoid arthritis (RA) for adult patients who have had an inadequate response or intolerance to methotrexate. While the Advisory Committee unanimously supported the efficacy of the 4-mg dose of baricitinib, it did not recommend approval of the 4-mg dose of baricitinib for the proposed indication based on the adequacy of the safety and benefit-risk profiles.">INDIANAPOLIS, April 23, 2018 /PRNewswire/ -- Eli Lilly and Company (LLY) and Incyte Corporation (INCY) announced today that the U.S. Food and Drug Administration's (FDA) Arthritis Advisory Committee recommended approval of the 2-mg dose of baricitinib, a once-daily oral medication for the treatment of moderately-to-severely active rheumatoid arthritis (RA) for adult patients who have had an inadequate response or intolerance to methotrexate. While the Advisory Committee unanimously supported the efficacy of the 4-mg dose of baricitinib, it did not recommend approval of the 4-mg dose of baricitinib for the proposed indication based on the adequacy of the safety and benefit-risk profiles.

Christi Shaw, president of Lilly Bio-Medicines. 'While we are disappointed with the Advisory Committee's assessment of the data for the 4-mg dose, we are confident in the positive benefit-risk profile of both the 2-mg and the 4-mg doses. We look forward to continuing our work with the FDA on our New Drug Application (NDA) and are hopeful that baricitinib will receive approval in the coming months.'">"We are confident that baricitinib, if approved, can help people in the U.S. manage the challenges of living with RA," said Christi Shaw, president of Lilly Bio-Medicines. "While we are disappointed with the Advisory Committee's assessment of the data for the 4-mg dose, we are confident in the positive benefit-risk profile of both the 2-mg and the 4-mg doses. We look forward to continuing our work with the FDA on our New Drug Application (NDA) and are hopeful that baricitinib will receive approval in the coming months."

Japan.">Baricitinib 2-mg and 4-mg doses are approved in more than 40 countries, including the member states of the European Union and Japan.

For both doses, the Advisory Committee voted to support the assessment that baricitinib's data provide substantial evidence of efficacy. For the 2-mg dose, the Advisory Committee voted in favor of the assessment that baricitinib's safety data adequately support its approval. For the 4-mg dose, the Advisory Committee voted against the assessment that baricitinib's safety data was adequate to support its approval based on the proposed indication.

The Advisory Committee's recommendation was based on baricitinib's global development program, which included four completed Phase 3 studies. In total, 3,492 patients, who represented a range of treatment experiences, received baricitinib in the global RA development program. The Phase 3 studies evaluated baricitinib's treatment impact related to RA signs and symptoms, physical function, joint damage progression and other patient-reported outcomes. The Phase 3 program also evaluated recognized risks for RA patients, including serious infection, malignancy, major adverse cardiovascular events (MACE), venous thromboembolism (VTE), and gastrointestinal perforations, along with key laboratory changes. The safety profile of baricitinib is based on 7,860 patient-years of exposure.

University of Oxford, an expert who attended the Advisory Committee Meeting. 'Baricitinib could be a promising option for RA patients in the U.S. who are not achieving adequate disease control with currently available treatments.'">"Despite advances in the management of RA over the last 20 years, which include early treatment, optimized use of traditional therapies for rheumatic disease and the advent of newer medications such as biologics, many patients are still struggling to meet treatment targets, and live with debilitating pain, fatigue and other symptoms of RA," said Peter Taylor, MA, PhD, professor, University of Oxford, an expert who attended the Advisory Committee Meeting. "Baricitinib could be a promising option for RA patients in the U.S. who are not achieving adequate disease control with currently available treatments."

The FDA is not required to follow the Advisory Committee's recommendation, but will consider it during its review of the NDA for baricitinib.

About Baricitinib

Baricitinib is a once-daily oral JAK inhibitor currently in clinical studies for inflammatory and autoimmune diseases. There are four known JAK enzymes: JAK1, JAK2, JAK3 and TYK2. JAK-dependent cytokines have been implicated in the pathogenesis of a number of inflammatory and autoimmune diseases, suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions, including rheumatoid arthritis.">**About Baricitinib**

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December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases. Baricitinib was submitted for regulatory review seeking marketing approval for the treatment of rheumatoid arthritis in the U.S., the European Union and Japan in 2016. Baricitinib was approved in the EU in February 2017 and in Japan in July 2017. In April 2017, the U.S. Food and Drug Administration issued a Complete Response Letter on the New Drug Application for baricitinib. To date, baricitinib has been approved in more than 40 countries and remains under review in several other markets.">In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases. Baricitinib was submitted

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